LevTech, Inc.

New Heights with Technology

Business Plan

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Confidential and Proprietary
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Core Technology

LT's technology utilizes superconductive levitation in schemes designed for the mechanical transmission of fluids (toxic and non-toxic) or the mixing of solutions in which a sterile and non-contaminated environment is required.

The majority of biopharmaceutical mixing technologies involve some sort of rotation impeller that must be mechanically supported and driven from outside the mixing vessel. Recently, there has been a strong effort to eliminate the external support and drive requirements by magnetically driving the impeller in applications where contamination and cleaning/sterilization requirements are severe.

LT has developed a *levitation mixer* that is far superior to all other mixing technologies. LT's key innovation is to utilize the unique nature of the magnetic interaction between *superconducting* and magnetic elements, thereby eliminating problematic dynamic seals and internal bearings in the mixing vessel.

Superconductivity has been around since 1911; however, the phenomenon has not been widely used in industry since temperatures approaching absolute zero were required to sustain the superconducting state. This situation made commercialization of superconductivity impracticable since liquid helium was required to cool devices.

In 1987, high temperature oxide superconductors (HTS) were discovered that required only the use of liquid nitrogen as a cryogen, which is much less expensive and easier to handle than liquid helium. LT utilizes ceramic crystals of a particular HTS ("YBCO") that, when cooled to 77 Kelvin, can ideally support an electrical current without any loss of energy.

When a magnet is attached to an impeller, as in LT's technology, and placed above thermally separated YBCO material, an electrical current is induced in the high temperature superconductor. This creates a magnetic field capable of levitating the impeller / magnet configuration. The use of a superconducting element provides levitation that is far more stable than conventional magnetic levitation devices. The levitated impeller / magnet can be remotely rotated using an external motor and magnet. This basic configuration can be applied in devices designed to mix fluids or suspensions, or propel fluids as in a pump. (See Illustration 1).

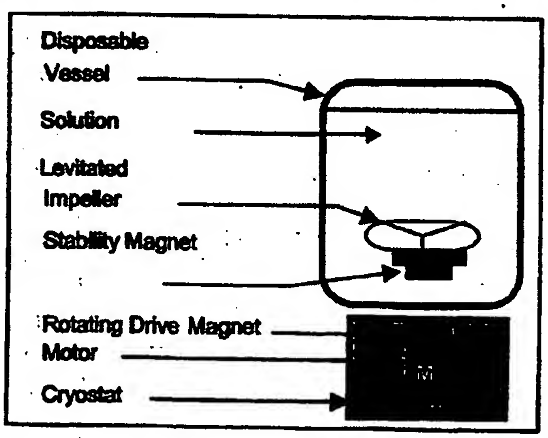

Illustration 1
LevTech Levitation Technology
Disposable Bag Configuration

Target Markets:

The following applications have been identified as strong candidates for the commercialization of LT's technology:

1. The mixing of clinical-grade biopharmaceutical solutions and suspensions in sterile disposable mixing/storage containers or rigid vats.
2. To pump bioprocessed materials and cellular biomass for crossflow filtration.
3. The sterile pumping or transport of blood and blood products:
   - During open-heart surgery as a cardiac assist pump.
   - Pre-surgical temporary artificial heart.
   - In blood bank facilities.
4. The largest potential market application of LT's technology would be in the industrial pump industry (e.g. oil, gas & water transmission pipelines). The benefits are that there would be minimal servicing, maintenance, or replacement costs associated with LT's levitation pumps.
5. The movement or transport of toxic solutions or infectious agents in hermetic pipes/vessels wherein environmental contamination is a major concern.
6. The sterile transport of ultra pure water for:
   - The cleansing of microprocessor chips.
   - The sterile insertion into pharmaceutical fluids for human injection.
   - Boiler feed in the power generation industry.
   - Flat panel display and micro-electromechanical systems (MEMS) manufacturing.
7. The inter-vacuum chamber movement of wafers during the manufacturing process using our levitation technology.
8. Levitation for the vibration isolation of clean rooms or laboratories used in the calibration, measurement and manufacture of highly delicate/sensitive instrumentation and components.

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Applied Markets:

Described below are the four market applications that management will simultaneously pursue. These applications have the highest probability for success because of the current level of LT's patent protection, the relative short time to market and size of the marketplace.

1. Bioprocess Mixing

Need for Clean Mixing

The biotechnology and pharmaceutical industries currently require an isolated or sterile environment for the mixing of clinical-grade solutions or suspensions in both research and manufacturing processes. These highly controlled mechanical systems must provide for the uniform distribution of ingredients in the final product, while simultaneously minimizing contamination. Product contamination or hazardous material leakage is a major health and financial concern to companies engaged in bioprocessing. For example, the manufacturers' cost of a single 10,000-liter mammalian cell culture batch can range up to $5,000,000.

Current Process

Today, state-of-the-art industrial mixing systems that provide the highest degree of non-contamination incorporate a reusable stainless steel/rigid vat with motor-driven mixers. There are two types—shaft driven and magnet driven.

Shaft Driven

One popular example employs an impeller that is coupled by a shaft to an externally mounted motor. The shaft penetrates into the vat via a dynamic seal. These seals are problematic since they are difficult to clean/replace and are susceptible to failure and leakage. Leakage is a serious problem when working with materials such as cytotoxic or infectious agents, solvents with low flash points and blood products. (See Illustration 2).

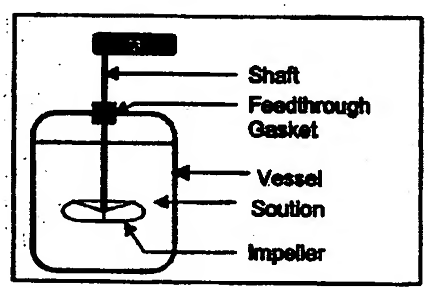


Illustration 2
Present Shaft Driven Impeller Configuration

A study, presented at the Interphex West Conference in October 8, 1996 by Jeffery Gambrill, Engineering Team Leader at LIGHTNIN, contained the following statements.

"With product contamination being the number one concerns in both the biotechnology and pharmaceutical industries, greater demands are being placed on conventional mixer technology. The conventional seals such as

mechanical, stuffing boxes and lip seals, which have been around for decades, can only control leakage; they can't prevent it."

Roller Bearing Magnet Drive

In an alternative design, a magnetically driven impeller is placed inside the vat with no penetrating shaft, but roller bearings must be mounted to the base to provide stable rotation of the impeller. (See Illustration 3). However, there are several significant drawbacks to this process:

1. Since the vats are reused for multiple applications, there is the potential of batch contamination because of improper cleaning/sterilization of the bearing assembly.
2. The high torque required for this bearing assembly, coupled with the need to circulate the suspensions/solutions around the bearings for cooling and lubrication can cause the denaturation of proteins and hemolisis of living cells, thus reducing product yields.
3. The bearings frequently deteriorate due to the corrosive reactions with water-based solutions causing additional product contamination.
4. The utilization of reusable containers is costly in terms of manpower and materials. Stedim estimates that the cost per use of this approach is approximately $400 for cleaning/sterilization and storage. Moreover, in situations where contract manufacturers are making ten to twenty different products, or a small biotech company that needs to make one or more different batches of clinical-grade material, and does not have the capital to invest in all-stainless or stainless/glass equipment for each product, the costs can be prohibitive.

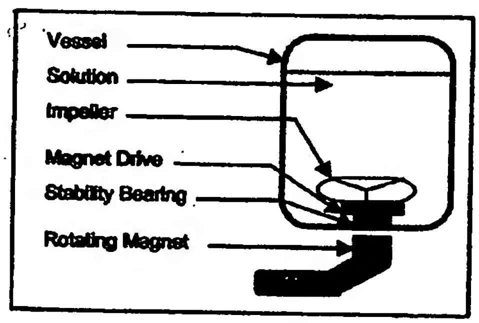


Illustration 3
Magnetic Driven Impeller
Stability Bearing Mode

Clearly, there is a need for new technology that would permit the integration of disposable processing bags for use in cases where the mixing of solutions and slurries needs to be done within a sterile, non-contaminated environment. LT has this technology. The following is an excerpt from an article appearing in Industry News 04/06/98:

"Cleaning, sterilization, and validating pharmaceutical manufacturing equipment are as inevitable as death and taxes. Bioprocess equipment cleaning has borrowed extensively from the larger pharmaceutical industry in this regard, plus developed its own set of protocols to deal with biocontaminants such as Pyrogens, DNA/RNA, and infectious agents. To reduce the cleaning and validation burden, bioprocessors are moving towards plastic storage systems as alternatives to glass and stainless steel. These vessels referred to as flexible

carboys or bioprocess container systems, are essentially high tech plastic bags that are discarded after use. Bag materials are chosen for inertness, strength, and barrier properties to prevent carbon dioxide from entering the carboy and moisture from exiting. The challenge has been to ensure a practical, reliable method of maintaining the sterility of fluids into and stored in these containers. Especially for handling non-critical fluids," says Millipore Corp. Director of Marketing Stephen Tingley, "companies are looking to replace glass and stainless steel tanks at sizes ranging from one liter up to 1000 liters. When this has been possible, cleaning and validation issues – at least as far as those vessels are concerned – go away. Today flexible carboys are used in about 50% of the large volume applications for non-critical fluids (media & buffers). The industry has readily accepted flexible carboys as storage vessels. Truly disposable manufacturing is still only a goal, but definitely within reach."

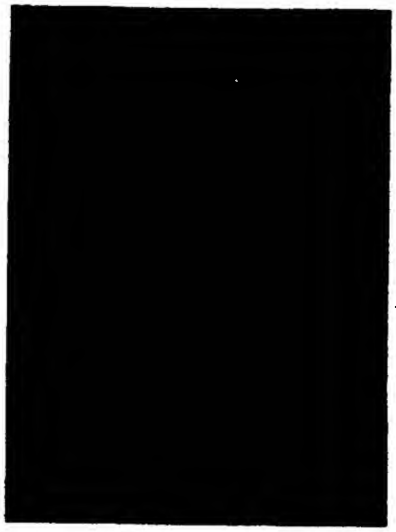
LevTech's technology now achieves this goal!

The mixing technologies mentioned above were developed for rigid vats and can not be applied to the utilization of flexible bioprocessing bags. Integrating LT's technology into the preparation of clinical-grade solutions via disposable bags will revolutionize a number of areas in biomedical processing. <u>LT's levitation mixer is compatible with flexible plastic bags and thus permits an incremental, substantial increase in the usage of plastic bioprocess bags in the biotech industry</u>.

A prototype of our technology has been constructed and is currently being used for demonstrations to potential investors, venture capital firms and potential licensees.

Appendix 3

Photos of Prototype Technology Models



Shaft Driven Mixer

This photo is a laboratory demonstration model showing a shaft driven impeller. Note that the rotating shaft, with impeller, is levitated off the bottom of the vessel.

The configuration shown lends itself to the use of disposable mixing bags that are presently in use for "clean" solution mixing operations. The shaft and impeller will be adapted to disposability along with the bag, thus achieving a sterile, single use mixing container for clinical-grade bio-pharmaceutics.

Pancake Driven Mixer

This photo is also of a laboratory demonstration model. It shows levitation technology isolating the pancake impeller. The configuration shown here could be used in mixing situations where it is desirable to keep the overhead clear from the drive motor. As is the case with the shaft driven mixer, disposable mixing bags with disposable impeller will be adapted for clinical-grade mixing operations.